IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation,	:	
Plaintiff/Counterclaim-Defendant,	:	
v.	:	**Civil Action No. 07-754 (GMS)**
BANNER PHARMACAPS INC. a Delaware corporation,	:	
Defendant/Counterclaim-Plaintiff.	:	

BANNER'S RESPONSE TO ABBOTT'S MOTION TO DISMISS
BANNER'S FIRST COUNTERCLAIM

George Pazuniak (DE # 478)
Anna Martina Tyreus (DE # 4771)
WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
222 Delaware Avenue, Suite 1501
Wilmington, Delaware 19801
Telephone: (302) 252- 4320
Email: GPazuniak@wcsr.com
Email: MTyreus@wcsr.com

Attorneys for Banner Pharmacaps Inc.

OF COUNSEL:

Charles J. Raubicheck
FROMMER LAWRENCE & HAUG, LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Page

Statutes

Rules

I. NATURE AND STAGE OF PROCEEDINGS

Abbott Laboratories ("Abbott") sued Banner Pharmacaps, Inc. ("Banner") on November 21, 2007 for allegedly infringing two Abbott patents. Banner answered on January 28, 2008, and counterclaimed for a declaratory judgment that it did not infringe the two Abbott patents. (D.I. 7 Counterclaim ¶¶ 7-15) Banner also counterclaimed that Abbott's suit was objectively baseless and an act of unfair competition. (D.I. 7 Counterclaim ¶¶ 16-20) On February 2, 2008, Abbott replied to Banner's First Counterclaim (D.I. 10), and moved to dismiss the Second Counterclaim (D.I. 11). Abbott's two patents at issue expired on January 29, 2008.

Abbott has filed, to date, three motions to dismiss. Abbott first filed a motion to dismiss Banner's Second Counterclaim of Unfair Competition. (D.I. 11) Abbott then filed a motion to dismiss its own claims. (D.I. 18). Now Abbott filed a motion to dismiss Banner's First Counterclaim. (D.I. 21)

II. SUMMARY OF THE ARGUMENT

Abbott ignores the Federal Circuit's holding in *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1242 (Fed. Cir. 2008), and district court authority in *Nat'l Semiconductor Corp. v. Linear Tech. Corp.*, 703 F.Supp. 845 (N.D. Cal. 1988), which support that a case or controversy continues to exist as to whether Banner infringed the patents at the time the complaint and counterclaims were filed. Non-infringement is a predicate to Banner's unfair competition Second Counterclaim and, therefore, neither the expiration of the patents nor Abbott's belated dismissal of its claims moots the non-infringement issue. Abbott injured Banner by filing the frivolous claim of infringement, regardless of whether Banner has now received FDA approval and access to the market. None of the cases cited by Abbott are directly on point, and none provide more direct authority than *Monsanto Co. v. Bayer Bioscience N.V.*, and *Nat'l Semiconductor Corp. v. Linear Tech. Corp.*

Further, even if Banner's First Counterclaim were to be dismissed as moot, Abbott's motion should still be denied, because Abbott seeks to have the dismissal be with prejudice. Abbott apparently moves for dismissal "with prejudice" in order to later argue some form of claim or issue preclusion based on the dismissal. Therefore, if the Court were to dismiss the First Counterclaim, it should expressly provide that dismissal is without prejudice to Banner's Second Counterclaim.

III. STATEMENT OF FACTS

Banner submitted new drug application 21-152 ("Banner's NDA") to obtain regulatory approval to sell valproic acid for treating epileptic seizures. (D.I. 7 Counterclaim ¶ 9) Banner's proposed drug was the same as, or equivalent to, Abbott's Depakene® -- i.e., both were valproic acid. However, Abbott did not identify in the FDA's Orange Book any patents associated with Depakene®. Thus. Banner stated in its Paragraph IV certification to Abbott:

> We note valproic acid is the active ingredient in Abbott's Depakene® capsule and syrup. Valproic acid is not covered by any unexpired United States patents, and Abbott has not listed any unexpired patents relative to Depakene® in the Orange Book.

(D.I. 15 Ex. 1A)[1] However, Abbott had another related FDA-approved epileptic drug, Depakote®, which is sodium valproate and valproic acid in a 1:1 molar relationship and formed during the partial neutralization of valproic acid with 0.5 equivalent of sodium hydroxide. (D.I. 7 Counterclaim ¶ 7) Depakote ®, like Banner's product but unlike Depakene®, is a time-release drug. In the FDA Orange Book, Abbott listed two patents as covering Depakote® -- U.S. Patent Nos. 4,988,731 ("the '731 patent") and 5,212,326 ("the '326 patent"). (D.I. 7 Counterclaim ¶ 8).

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[1] Abbott blatantly distorts the record by stating that "Banner did not select as its reference-listed drug one of the many FDA-approved valproic acid products." (Abbott Br. at 4). As the above quotation from Banner's certification demonstrates, Banner did reference FDA-listed valproic acid product, Depakene®, but, in addition cited Depakote® at the FDA's suggestion.

All the claims of both patents are limited solely to an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid. (D.I. 7 Counterclaim ¶¶ 11, 12)

Because Abbott had cited the two patents in conjunction with the related Depakote® drug and Depakote® was given in time-release dosages, the FDA advised Banner to cite Depakote® in its Paragraph IV certification. Banner did so, and clearly explained in that certification that neither patent can be infringed by its proposed valproic acid drug, because all the claims of both cited Abbott patents are limited to an oligomer of combining sodium valproate and valproic acid in a 1:1 molar relationship.

There could be no reasonable or legitimate question that Banner's proposed product did not infringe either Abbott patent, because patent claims directed to a drug combination can not be infringed by a single drug. The fact that Abbott did not cite either patent in conjunction with Depakene® clearly evidences Abbott's recognition that its patents were not implicated by Banner's proposed drug. Indeed, Abbott's failure to cite any patents in conjunction with its Depakene® valproic acid drug estopps Abbott from arguing that any legitimate claim could be made that Banner's proposed valproic acid was infringing.

Nevertheless, despite its own manifest recognition and estoppel, Abbott sued Banner for infringing the two patents. The effect of the lawsuit was to delay Banner's entry into the market for several months, causing damage to Banner, including both loss of profits and the defense of this action.[2]

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2 By filing the infringement suit, Abbott ensured that the 30 month stay was triggered under the Act which precluded Banner from achieving final FDA approval until after the patents expired. That delay between the lawsuit filing and patent expiration was over two months, during which time Banner could have been establishing its place as a leader in the marketplace among generic companies. In addition, by filing the frivolous suit, Abbott was able to invoke the statutory six-month extension of monopoly for pediatric uses. 21 U.S.C. § 355a(c)(2)(B). The result was a an

IV. ARGUMENT

A. Standard of Review

Abbott mounts a facial attack on Banner's first counterclaim, arguing that no subject matter jurisdiction exists because the patents are now expired. "In reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply." *Adkins v. Rumsfeld*, 450 F.Supp.2d 440, 445 (D. Del. 2006). The Court must accept all factual allegations in the Answer and Counterclaim as true. *Id.*

B. A Case or Controversy Exists As To Whether Banner's Product Infringed Abbott's Patents When The Complaint And Counterclaims Were Filed

1. Abbott Ignores Governing and Most Relevant Authority

Abbott's arguments that there is no longer any case or controversy as to the First Counterclaim are unavailing in light of the Federal District decision in *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1242 (Fed. Cir. 2008) and the district Court decision in *Nat'l Semiconductor Corp. v. Linear Tech. Corp.*, 703 F.Supp. 845 (N.D. Cal. 1988). In *Monsanto v. Bayer*, Monsanto sought a declaratory judgment that three Bayer patents were not infringed, but Bayer subsequently dismissed with prejudice its infringement claims as to those three patents by filing a Statement of Non-Liability, covenanting not to sue Monsanto for past, present, or future infringement of these patents. The Federal Circuit noted that the filing of such a covenant may divest the court of jurisdiction over a declaratory judgment action regarding the disclaimed patents, citing the authorities noted by Abbott, but the Federal Circuit then also noted that Monsanto had pending claims for attorney fees based on Bayer enforcing allegedly inequitably-procured patents. The Federal Circuit stated that the court retained Article III jurisdiction to

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8-month delay in Banner's product entering the market – the two months delay between filing the lawsuit and the expiration of the patents, and the six-month statutory delay caused by the lawsuit.

consider the attorney fees, and, therefore, it had jurisdiction to determine whether the patents were inequitably procured, and

> A district court has no discretion to decide whether a patent is unenforceable once it enters a finding of inequitable conduct. . . . As a result, jurisdiction to decide whether a patent was obtained through inequitable conduct necessarily includes the jurisdiction to declare a patent unenforceable as a result of that inequitable conduct.

Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d at 1242.

This case can not be principally distinguished from the *Monsanto* decision. The Court has jurisdiction over Banner's unfair competition Second Counterclaim, just like the *Monsanto* court had jurisdiction to award attorney fees. In *Monsanto*, an element of the claim for attorney fees was that the patents were procured through inequitable conduct, while in this case, non-infringement is an element of Banner's unfair competition Counterclaim. Finally, just as in *Monsanto* the finding of inequitable conduct in the course of determining the award of attorney fees required the court to find the patents unenforceable, so here the finding of non-infringement in the course of determining the unfair competition Counterclaim must result in a finding that Banner's drug did not infringe the two patents.

Indeed, a very similar issue here was addressed in *Nat'l Semiconductor Corp. v. Linear Tech. Corp.*, 703 F.Supp. 845 (N.D. Cal. 1988). In *Nat'l Semiconductor*, plaintiff sued on several patents. Defendant counterclaimed for a declaration that one of the patents was invalid and unenforceable, and counterclaimed for antitrust, patent misuse and unfair competition pedicated on the invalidity and unenforceability of the patent. The Plaintiff then dedicated that patent to the public, and moved to dismiss defendant's declaratory judgment claim of non-infringement, invalidity, and unenforceability. The Court concluded that the declaratory judgment of non-infringement was moot, because the non-infringement was not related to any

remaining case or controversy. However, the court refused to dismiss the declaratory judgment as to invalidity and unenforceability in view of the pending counterclaims for which those were critical elements. The Court explained:

> [I]nvalidity, inequitable procurement, and bad faith enforcement of invalid patents are predicates to Linear Technology's antitrust and unfair competition counterclaims as they apply to the '059 patent. Linear Technology will need a ruling that the '059 patent was invalid prior to its dedication to the public in order to establish that NSC had the requisite intent to foster antitrust violations and patent misuse.

Id. at 850. The same is true here. Non-infringement is an element of Banner's unfair competition counterclaim, and, therefore, is not dismissable for lack of case or controversy.

2. Abbott Arguments Are Misplaced

In light of the above authorities, Abbott's allegation that there is no case or controversy can not be sustained. Abbott's other arguments are then easily disposed.

Abbott's citation of *Pfizer, Inc. v. Ranbaxy Labs Limited*, 525 F. Supp.2d 680 (D. Del. 2007) is not instructive. The issue in *Pfizer* was whether declaratory judgment jurisdiction existed for a claim of non-infringement of a patent that was pending reissue. The Court concluded that a patent must exist and be presently enforceable against a declaratory judgment plaintiff, as opposed to pending in the PTO. *Id.* at 686. Here, in contrast, Abbott already asserted its patent against Banner and the injury already occurred.

Abbott argues that *Merck & Co., Inc. v. Apotex, Inc.*, 2008 WL 2753378 (Fed. Cir. 2008), affirming *Merck & Co., Inc. v. Apotex, Inc.*, 488 F.Supp.2d 418 (D. Del. 2007), "dooms Banner's claim." To the contrary, *Merck* was different from *Monsanto*, because no other issue existed in *Merck*. In *Merck*, this Court recognized that jurisdiction may still exist if plaintiff could "allege personal injury fairly traceable to defendant's allegedly unlawful conduct and likely to be re-dressed by the requested relief." *Merck*, 488 F. Supp.2d at 423 (citations omitted). This case is

distinguishable from the *Merck* facts, and similar to the above *Merck* exception, because of the unfair competition counterclaim, which seeks relief for "personal injury fairly traceable to [Abbott]'s allegedly unlawful conduct and likely to be re-dressed by the requested relief." A finding of non-infringement would remedy these injuries because it satisfies one element of the unfair competition claim. *See Merck & Co., Inc. v. Apotex, Inc.*, 2008 WL 2753378 (Fed. Cir. 2008) (affirming the district court's dismissal of suit but recognizing that "a justiciable Article III controversy may continue to exist between a patentee drug company and a Paragraph IV ANDA filer in the context of the Hatch-Waxman Act even after the patentee drug company has granted the Paragraph IV ANDA filer a covenant not to sue.")

Equally unhelpful to the pertinent issue, but ultimately lending credence to Banner's counterclaims, Abbott cites to *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000). In *Bayer*, the Federal Circuit affirmed a summary judgment of non-infringement because the specification in Elan's ANDA "defines its product in a way that directly addresses the question of infringement." *Id.* at 1249. Similarly, Banner sent Abbott a letter detailing why its product does not infringe Abbott's two patents. *See* D.I. 15 Ex. 1A ("Banner's proposed product contains valproic acid in an anteric soft gelatin capsule. The active ingredient in Abbott's Depakote® delayed release tablets is divalproex sodium, a related but distinct chemical entity from valproic acid.") As detailed in Banner's Response to Abbott's Motion to Dismiss Banner's Second Counterclaim, merely because a Paragraph IV certification can be an artificial act of infringement, a party is not granted an unfettered right to file frivolous lawsuits. (D.I. 15)

Abbott finally argues that the Paragraph IV certification somehow converts to a Paragraph II certification to destroy Article III jurisdiction. But the issue is not whether Banner is presently infringing, but whether Banner was infringing when Abbott sued Banner and Banner

counterclaimed. Just as the *Monsanto* Court found the covenant not to sue did not destroy jurisdiction, any conversion from Paragraph IV to II also does not alter the court's jurisdiction to determine the live issues of unfair competition and its attendant determination of whether Banner's proposed product was infringing. Even with a conversion, there was still jurisdiction when Abbott filed the present action and when Banner counterclaimed. This Court obtained jurisdiction over the First Counterclaim because it is a declaratory judgment for non-infringement, and over the Second counterclaim under 28 U.S.C. §1367(a), and those counterclaims are now stand-alone bases for jurisdiction, even if Abbott's original claims are now moot because of the conversion. The issue is whether the court has jurisdiction over the counterclaims, and whether the original jurisdiction remains is an irrelevancy. It is common that Plaintiffs' actions become moot, but the counterclaims proceed in light of their own jurisdictional basis.

C. Abbott Is Not Entitled to Dismissal With Prejudice

Abbott seeks to dismiss the non-infringement First Counterclaim with prejudice. (D.I. 22 at 9) Even if the Counterclaim should be otherwise dismissed, the Court should either dismiss without prejudice or otherwise clarify that the dismissal is without prejudice to the unfair competition Second Counterclaim. Granting Abbott's requested dismissal with prejudice could inadvertently lead to a claim of issue or claim preclusion.

"Dismissal with prejudice constitutes an adjudication of the merits as fully and completely as if the order had been entered after trial." *Gambocz v. Yelencsics*, 468 F.2d 837, 840 (3d Cir.1972) (citing *Lawlor v. National Screen Service Corp*., 349 U.S. 322, 327 (1955)). Although Banner does not concede the accuracy of the argument, a dismissal with prejudice resulting in a finding on the merits that Banner's product infringes Abbott's two patents could preclude Banner from arguing that the lawsuit by Abbott was frivolous and an unfounded

attempt to keep Banner off the market. *Cf, Bailey v. United States*, 2004 WL 386593 (Fed. Cir. 2004) (rejecting the government's argument that plaintiff's claim was barred by res judicata because it involved the same set of transactional facts as a separate district court claim that was dismissed on the merits by a voluntary dismissal with prejudice). Unless otherwise stated in an Order, an involuntary dismissal is a dismissal with prejudice under FED. R. CIV. P. 41(b).[3] If this Court enters an Order dismissing Banner's First Counterclaim, Banner respectfully requests the dismissal is without prejudice so as to not preclude Banner's Second Counterclaim of unfair competition. In addition, Banner requests the Court allow Banner to amend its Second Counterclaim to properly incorporate the facts pled under the first counterclaim.

D. Banner Was Injured By The Delay Into The Marketplace

Abbott attempts to portray an "all-is-right-in-the-world" scenario by emphasizing that Banner now has FDA approval and is soon entering the marketplace. But the damage is already done and it is that injury for which Banner seeks to be compensated in its unfair competition counterclaim. As set out in the counterclaims, Banner suffered a legally recognizable injury by being blocked from the marketplace. (D.I. 7 Counterclaims ¶¶ 18-19); *See Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc*., 527 F.3d 1278, 1291 (Fed. Cir. 2008) (recognizing a "restraint on the free exploitation of non-infringing goods," as an injury-in-fact). And that injury was a direct result of Abbott's actions.

V. CONCLUSION

In the world of generic pharmaceutical drugs, expedient entry into the marketplace is of utmost importance. Abbott's frivolous suit improperly kept Banner from the marketplace for over 9 months. A finding of non-infringement at the time Abbott filed its suit and Banner filed

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3 Abbott has replied to Banner's counterclaims, so Banner can not voluntarily dismiss its first counterclaim under Fed. R. Civ. P. 41(c).

its counterclaims is a necessary step in allowing Banner to recover for its injury. Whether this determination is made in the context of a counterclaim for a declaratory judgment of non-infringement or in a counterclaim of unfair competition is irrelevant, so long as Banner is permitted to make its case.

Dated: August 25, 2008

By: /s/ *AnnaMartina Tyreus*

George Pazuniak (DE # 478)
Anna Martina Tyreus (DE # 4771)
WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
222 Delaware Avenue, Suite 1501
Wilmington, Delaware 19801
Telephone: (302) 252- 4320
Email: GPazuniak@wcsr.com
Email: MTyreus@wcsr.com

Attorneys for Banner Pharmacaps Inc.

OF COUNSEL:

Charles J. Raubicheck
FROMMER LAWRENCE & HAUG, LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

CERTIFICATE OF SERVICE

I, AnnaMartina Tyreus, hereby certify that on August 25, 2008, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, and copies were caused to be served upon the following counsel of record via electronic mail:

Paul E. Crawford, Esquire
Connolly, Bove, Lodge & Hutz
The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899
(302) 658-9141
pcrawford@cblh.com
Attorney for Plaintiff

/s/ *AnnaMartina Tyreus*_____
AnnaMartina Tyreus